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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,742

09/12/2003

Eva Rojer

Strom.7274

9486

7590 10/28/2008  
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EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

10/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/661,742	ROJER, EVA	
	<b>Examiner</b>	<b>Art Unit</b>	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30,32-36,38-40 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-30,32-36,38,40 and 42-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/7/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

#### **RE: Rojer**

1. Applicant's response filed on 8/7/2008 is acknowledged. Claims 1-30, 32-36, 38-40 and 42-44 are pending. Claims 31, 37, 41 and 45-50 have been cancelled. Claims 1-30, 32-36, 38, 40 and 42-44 have been withdrawn from consideration as being drawn to non-elected inventions. Claim 39 has been amended.
2. Claim 39 is under examination.

#### ***Priority***

3. Applicant's statement that the applicant is in the process of obtaining a certified copy of the priority document is acknowledged.

#### ***Information Disclosure Statement***

4. It is noted that the reference DE 1974725A1 (in German) listed in the information disclosure statement (IDS) filed 9/12/2003 is not considered because the IDS does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of DE 1974725A1.
5. The information disclosure statement filed 8/7/2008 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each

patent, publication, or other information listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered as to the merits as it pertains to the foreign prior art DE 19742725A1 which is in German.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

***Objection Withdrawn***

6. The objection to the Drawings filed on 1/20/04 because the label for the X-axis in Figure 8 is not in English is withdrawn in view of applicant's amendment to the Drawings.
7. The objection to the disclosure because the Brief Description of the Drawings does not reference Figure 1A, 1B and 1C, and the Brief Description of Drawing is not consistent of the Drawing is withdrawn in view of applicant's amendment to the Drawings and the specification.
8. The objection to the first line of the specification is withdrawn in view of applicant's amendment to the specification.
9. The objection to claim 31, 37, 39, 41 and 45-50 is withdrawn in view of applicant's cancellation of the claims 31, 37, 41 and 45-50 and amendment to claim 39.

***Rejections Withdrawn***

10. The rejection of claims 31, 37, and 47-50 under 35 U.S.C. 112, second paragraph because the claims do not set forth any steps involved in the method/process is withdrawn in view of applicant's cancellation of the claims.

11. The rejection of claims 31, 37, and 47-50 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101 is withdrawn in view of applicant's cancellation of the claims.

12. The rejection of claims 31, 37, 39, and 45-51 under 35 U.S.C. 102(b) as being anticipated by Nawata et al. (Electrophoresis, 1999, 20: 614-617) is withdrawn in view of applicant's cancellation of the claims 31, 37 and 45-51 and amendment to claim 39.

13. The rejection of claims 37, 39, 41, and 45-48 under 35 U.S.C. 102(b) as being anticipated by Matsuda et al. (Cancer, 1990, 65: 2261-2265) is withdrawn in view of applicant's cancellation of the claims 31, 37 and 45-51 and amendment to claim 39.

14. The rejection of claims 37, 39, and 45-48 under 35 U.S.C. 102(b) as being anticipated by Cataltepe et al. (Clin. Chim. Acta, 2000, 295:107-127) is withdrawn in

view of applicant's cancellation of the claims 31, 37 and 45-51 and amendment to claim 39.

***Response to Arguments***

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

15. The rejection of claim 39 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing the presence or absence of a squamous cell carcinoma in a human comprising detecting SCCA1 protein or SCCA2 protein in a sample of said human, does not reasonably provide enablement for a method for diagnosing the presence or absence of a squamous cell carcinoma in a human comprising detecting the SCCA1/SCCA2 fusion protein in a sample of said human is maintained.

The response states that a western blot experiment showing that one of the monoclonal antibodies (S106) disclosed in the specification on p9, 1.31 and in Example 5, actually binds to fusion proteins present in human cancer cells has been conducted.

Applicant's arguments have been carefully considered but are not persuasive to overcome the rejection. It is noted that the specification does not have a section 1.31. The specification at page 9 discloses DNA analysis. Although Example 5 discloses antibodies that bind specifically to SCCA1/SCCA2 fusion protein, such as SCC106, no S106 is mentioned. Applicant mere statement that the antibody S106 binds to fusion proteins in cancer cell lines is not sufficient to overcome the rejection because in the absence of factual evidence, the examiner is unable to compare the steps, materials,

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and conditions used in applicant's experiments with those disclosed in the application to make sure that they are commensurate in scope (see MPEP 2164.05). Applicant may submit factual affidavits under 37 CFR 1.132 or cite references to show that the claimed invention was enabling as of the filing date (see MPEP 2164.05). Furthermore, the specification does not disclose an antibody that binds only to the fusion protein SCCA1/SCCA2, and has no affinity for SCCA1 or SCCA2 (emphasis added). Even the SCC106 antibody binds at certain degree to SCCA2 (see Figure 7). Applicant has not shown that the fusion protein SCCA1/SCCA2 is differentially expressed in sample of a cancer patient as compared to sample of a normal subject. Since the instant claim is drawn to a method for diagnosing the presence or absence of a squamous cell carcinoma in a patient, one skilled in the art would reasonably conclude that the specification has not enabled the invention as claimed. For the foregoing reasons, the rejection is maintained.

***New Grounds of Objections******Drawings***

16. The amendment filed 8/7/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Figures 8 and 9. Moreover, applicant did not point out the specific pages in the disclosure where the

support can be found. Although the specification provides brief description to the figures, no actual data was disclosed in the original disclosure.

If applicant believes that support for Figures 8 and 9 is present in the specification, claims or drawing as originally filed, applicant must, in responding to this action, point out with particularity, where such support may be found.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Conclusion***

17. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/  
Examiner, Art Unit 1643

/Christopher H Yaen/  
Primary Examiner, Art Unit 1643